Section 6 - 510(k) Summary

6.1 Classification

6.2 Submitter/Contact

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Prepared: 4/8/2003

6.3 Device Name

Proprietary Name: Olympic CFM 6000
Common Name: EEG Monitor
Classification Name: Electroencephalograph per 21 CFR 882.1400, Class II, 84GWQ, Neurology

6.4 Predicate Device

Olympic Medical Lectromed Cerebral Function Monitor (K020335).

6.5 Device Description

The Olympic CFM 6000 consists of two main components: A Data Acquisition Module and a Main System module. The Data Acquisition Module is used to connect the patient electrode leads, amplify the signal, and perform the analog-to-digital conversion. The Main system accepts data from the amplifier, processes and stores the signal, and displays the CFM, impedance, and EEG traces and provides the user interface for control of the device.

6.6 Intended Use

The Olympic CFM 6000 is intended to monitor the state of the brain by acquisition of EEG signals in the intensive care unit, operating room, and for clinical research.

6.7 Comparison to Predicate Device

The Olympic CFM 6000 is a digital implementation of the predicate device. All analog signal processing and display provided in the predicate device have been reproduced using digital filter and display technology in the Olympic CFM 6000. Additional convenience features have been added.

6.8 Summary of Comparison Tests

Comparison tests were performed using both bench and clinical input data to demonstrate that the output of the CFM 6000 is clinically identical to that of the predicate device.

6.9 Safety and Standards

The device is designed to meet at least the following safety standards:

- IEC CAN\CSA 60601-1-1, class I, Type BF, Medical Electrical Equipment, Part 1: General Requirements for safety
- IEC 60601-1-2:2000, Medical electrical equipment – General requirements for safety. Electromagnetic compatibility
- UL 2601 -1 Standard for Safety for Medical Electrical Equipment, Part 1, General Requirements for Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 14 2003

Edward B. Weiler, Ph.D.
Vice President, Research and Development
Olympic Medical Corporation
5900 First Avenue South
Seattle, Washington 98108

Re: K031149
Trade/Device Name: Olympic CFM 6000
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: II
Product Code: GWQ
Dated: April 8, 2003
Received: April 15, 2003

Dear Dr. Weiler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 - Indications for Use

510(k) NUMBER (IF KNOWN): K 031149

DEVICE NAME: Olympic CFM

INDICATIONS FOR USE:

The Olympic CFM 6000 is intended to be used by a variety of clinicians to acquire and utilize EEG signals, when used in conjunction with other clinical data, in intensive care areas, Operating Room, Emergency Room, and clinical research lab:

- to monitor the state of the brain
- for determination of, and long-term monitoring of, the neurological status of patients that may have suffered an hypoxic-ischemic event.
- for monitoring of neurological status to assist in the clinical management and treatment of the patient by observing how the treatment affects the neurological status as shown by the CFM.
- to assist in the prediction of neurological outcome
- to monitor and record frequency and intensity of seizures to assist in management of anti-convulsive therapy.
- to assist in the prediction of severity of Hypoxic-Ischemic Encephalopathy and long-term outcome in infants who have suffered an hypoxic-ischemic event.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031149